UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT GREENEVILLE

KIMBERLY JOAN ELLIS, and WILLIAM RAY ELLIS,	)	
Plaintiffs,	)	
v.	)	No. 2:20-CV-223-CEA-HBG
ETHICON, INC., et al.,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This case is before the undersigned pursuant to 28 U.S.C. § 636, the Rules of this Court, and Standing Order 13-02.

Now before the Court is Defendants' Renewed Motion to Limit the Opinions of Pathologist Elizabeth A. Laposata, M.D. ("Renewed Motion") [Doc. 93] and Defendants' Motion to Limit the Case-Specific Opinions of Bruce Rosenzweig, M.D. ("Motion to Limit") [Doc. 95]. The parties appeared before the undersigned for a motion hearing on July 2, 2021. Attorneys Timothy Jackson and Justin Day appeared on behalf of Plaintiffs. Attorneys Amy Pepke and Kari Sutherland appeared on behalf of Defendants. Accordingly, for the reasons discussed below, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motions [**Docs. 93, 95**].

I. BACKGROUND

On March 9, 2008, Plaintiff Kimberly Ellis ("Plaintiff") underwent an operation at the Morristown Hamblen Hospital in Morristown, Tennessee, by Dr. Penny Knight, who implanted a TVT-O device ("TVT-O") [Doc. 1].[1] Later, on September 21, 2010, Plaintiff underwent a second

[1] Although there are two Plaintiffs in this case, the Court will use "Plaintiff" when referring to only Plaintiff Kimberly Ellis.

operation at Mercy Medical Center in Knoxville, Tennessee, performed by Dr. McCauley, who implanted the Prolift +M.

Plaintiff claims to have suffered from pudendal nerve damage, piriformis syndrome, pelvic pain, post-traumatic stress disorder ("PTSD"), sexual dysfunction, depression, opioid dependency, infections, memory loss, uncontrollable bladder, panic attacks, and right hip pain from the TVT-O and Prolift +M implant procedures. In addition, Plaintiff claims that she continues to suffer bodily and emotional injuries from the implant procedures and from the defects in the TVT-O and the Prolift +M.

Relevant to the instant matter, Plaintiffs retained Elizabeth Laposata, M.D., a pathologist, and Bruce Rosenzweig, M.D., a urogynecologist, to testify as experts in this matter. Defendants have challenged both experts' opinions.

II. STANDARD OF REVIEW

"Federal Rule of Evidence 702 obligates judges to ensure that any scientific testimony or evidence admitted is relevant and reliable." *Kumho Tire Co., Ltd. v. Carmichael,* 526 U.S. 137, 147 (1999) (quoting *Daubert v. Merrell Dow Pharma., Inc.*, 509 U.S. 579, 589 (1993)). Specifically, Rule 702 provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and

(d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

In *Daubert,* the Supreme Court of the United States stated that a district court, when evaluating evidence proffered under Rule 702, must act as a gatekeeper, ensuring "that any and all scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589. The *Daubert* standard "attempts to strike a balance between a liberal admissibility standard for relevant evidence on the one hand and the need to exclude misleading 'junk science' on the other." *Best v. Lowe's Home Ctrs., Inc.*, 563 F.3d 171, 176–77 (6th Cir. 2009).

The factors relevant in evaluating the reliability of the testimony, include: "whether a method is testable, whether it has been subjected to peer review, the rate of error associated with the methodology, and whether the method is generally accepted within the scientific community." *Coffey v. Dowley Mfg., Inc.*, 187 F. Supp. 2d 958, 970-71 (M.D. Tenn. 2002) (citing *Daubert*, 509 U.S. at 593–94). Rule 702 inquiry as "a flexible one," and the *Daubert* factors do not constitute a definitive checklist or test. *Kumho Tire Co.*, 526 U.S. at 138-39 (citing *Daubert*, 509 U.S. at 593); *see also Heller v. Shaw Indus., Inc.,* 167 F.3d 146, 152 (3d Cir. 1999) (explaining that these factors "are simply useful signposts, not dispositive hurdles that a party must overcome in order to have expert testimony admitted").

"Although *Daubert* centered around the admissibility of scientific expert opinions, the trial court's gatekeeping function applies to all expert testimony, including that based upon specialized or technical, as opposed to scientific, knowledge." *Rose v. Sevier Cty., Tenn.*, No. 3:08-CV-25, 2012 WL 6140991, at *4 (E.D. Tenn. Dec. 11, 2012) (citing *Kumho Tire Co.*, 526 U.S. at 138-39). "[A] party must show, by a 'preponderance of proof,' that the witness will testify in a manner that will ultimately assist the trier of fact in understanding and resolving the factual issues involved in

the case." *Coffey*, 187 F. Supp. 2d at 70-71 (quoting *Daubert*, 509 U.S. at 593-94). The party offering the expert has the burden of proving admissibility. *Daubert,* 509 U.S. at 592 n. 10.

Moreover, the Supreme Court has explained that in determining "whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact," the court must assess "whether the reasoning or methodology underlying the testimony is scientifically valid and whether it can properly be applied to the facts in issue." *Id.* at 592–93. "Furthermore, the court must examine the expert's conclusions in order to determine whether they can reliably follow from the facts known to the expert and the methodology used." *In re Diet Drugs*, No. MDL 1203, 2001 WL 454586, at *7 (E.D. Pa. Feb. 1, 2001) (citing *Heller,* 167 F.3d at 153).

Further, a court should "exclude proffered expert testimony if the subject of the testimony lies outside the witness's area of expertise." *In re Diet Drugs*, 2001 WL 454586, at *7 (quoting 4 Weinstein's Fed. Evid. § 702.06[1], at 702–52 (2000)). This simply means that "a party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue." *Id.* (other citations omitted).

Finally, "the court will not exclude expert testimony merely because the factual bases for an expert's opinion are weak." *Andler v. Clear Channel Broad., Inc.*, 670 F.3d 717, 729 (6th Cir. 2012) (quotation marks and citations omitted). Exclusion is the exception, not the rule, and "the gatekeeping function established by *Daubert* was never 'intended to serve as a replacement for the adversary system.'" *Daniels v. Erie Ins. Group*, 291 F. Supp. 3d 835, 840 (M.D. Tenn. Dec. 4, 2017) (quoting *Rose v. Matrixx Initiatives, Inc.*, No. 07–2404–JPM/tmp, 2009 WL 902311, at *7 (W.D. Tenn. March 31, 2009)) (other quotations omitted). Rather, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert,* 509 U.S. at 596.

Rule 702 does not "require anything approaching absolute certainty." *Daniels*, 291 F. Supp. 3d at 840 (quoting *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 671–72 (6th Cir. 2010)).

III. ANALYSIS

The Court has considered the parties' filings and the oral arguments presented at the motion hearing. Accordingly, for the reasons explained below, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Motions [**Docs. 93 and 95**].

The Court will first address Defendants' challenges to Dr. Laposata's opinions and then turn to Defendants' challenges to Dr. Rosenzweig's opinions.

A. Dr. Laposata

Defendants assert three challenges to Dr. Laposata's opinions. First, Defendants argue that Dr. Laposata is not qualified to opine on the supposed biochemical changes in the mesh after implantation, such as degradation and the release of harmful substances into the tissue. Second, Defendants argue that Dr. Laposata is not qualified to offer opinions regarding Plaintiff's pain. Finally, Defendants state that Dr. Laposata improperly offers general causation opinions.

The Court will address the challenges to Dr. Laposata's qualifications and then turn to the challenge with respect to her general causation opinions

1. Qualifications

As mentioned above, Defendants argue that Dr. Laposata is not qualified to render opinions on the biochemical changes in the mesh after implantation and Plaintiff's pain. With respect to the biochemical changes, Defendants state that Dr. Laposata is a forensic pathologist with prior experience as a medical examiner, and she acknowledged that she is not an expert in mesh degradation. Defendants argue that Dr. Laposata admitted that chemical degradation would be within the expertise of a bioengineer. Similarly, with respect to Dr. Laposata's opinions about

Plaintiff's pain, Defendants argue that she is not qualified to render such an opinion because she is not a clinical physician, and she does not treat or manage pain. Defendants also state that Dr. Laposata never observed Plaintiff and that Dr. Laposata only observed pathology slides.

Plaintiffs assert that Dr. Laposata is qualified to testify about the above subjects and that she was allowed to offer similar testimony based on her expertise and observations, citing to *Meade v. Ethicon*, No. 4:20-CV-00694-KGB, 2020 WL 6395814, (E.D. Ark. Nov. 2, 2020).

During the motion hearing, Defendants stated that they do not object to Dr. Laposata testifying to what she observed on the pathology slides and that her observations were consistent with degradation mesh. Defendants argued, however, that Dr. Laposata cannot opine that the mesh degraded because she is not a bioengineer. In addition, Defendants stated that Dr. Laposata is permitted to opine on what she observed, which is consistent with pain, but she cannot opine that certain issues were the causes of Plaintiff's pain. Defendants maintained that Dr. Laposata is a pathologist and that she is not qualified to opine on a diagnosis.

Plaintiffs argued that Dr. Laposata saw signs of degradation. Plaintiffs stated that they do not intend to offer Dr. Laposata as a degradation expert and that she will not testify on why the mesh degraded or what caused the mesh to degrade. Plaintiffs argued that Dr. Laposata can testify to what she saw. In addition, Plaintiffs responded that they anticipate that Plaintiff will describe the pain that she suffers, but to the extent Dr. Laposata offers opinions in this area, she is qualified to describe what she observed about Plaintiff's condition.

In Dr. Laposata's expert report, she explains that she is a pathologist who studies the effects of diseases and injuries on the tissues, organs, and fluids of the human body. [Doc. 93-2 at 3]. She explains that pathology includes examining tissues under the microscope to diagnose changes in those tissues that result from disease and/or injury and that the subspeciality of forensic

pathology encompasses all aspects of pathology in addition to the concentrations of concerns that establish the causes of injuries and/or disease processes often focusing on questions generated in the legal arena. [Doc. 93-2 at 3]. Dr. Laposata opines that polypropylene mesh degrades and that the degraded mesh surface can release harmful substances into the surrounding tissue. *See* [Doc. 94 at 3] (citing [Doc. 93-2 at 5-6, 13, 15-6]). In addition, Dr. Laposata opines, "Pain can be generated by the nerves noted to be encased within the fibrous tissue closely associated with the mesh filaments" and that Plaintiff's "chronic pelvic pain and dyspareunia . . . [are] related to the mesh." [*Id.* at 15].

The Court finds that Dr. Laposata is not qualified to opine that the mesh degraded or that degraded mesh releases chemicals as she is a pathologist and not a bioengineer. The Court further finds, however, that Dr. Laposata may opine that she saw signs consistent with degradation, and as a pathologist, she may explain her observations on the pathology slides, including any adverse effects on the surrounding tissue. Similarly, the Court finds that Dr. Laposata cannot opine that Plaintiff's alleged conditions (*i.e.*, chronic pelvic pain and dyspareunia) are related to the mesh as she is a pathologist and not a clinical physician, but Dr. Laposata is qualified to opine on how pain is generated and whether her observations are consistent with pain. Accordingly, the Court finds that Defendants' arguments are well taken, and the Motion on this issue is **GRANTED**.

2. Causation

Defendants assert that in Dr. Laposata's expert report, her opinions go beyond her designation as a case-specific expert and that she has improperly provided general causation opinions. Defendants state that the MDL court precluded plaintiffs from eliciting general causation opinions from physicians who were only disclosed as case-specific experts. In addition,

Defendants state that several of Dr. Laposata's general causation opinions are not related to her findings as to Plaintiff.

Plaintiffs state that Dr. Laposata simply provided a foundational basis for her opinions and what she observed in her report. Plaintiffs contend that Dr. Laposata will only offer opinions and testimony that are applicable to Plaintiff's case.

During the hearing, Defendants stated that they were not clear if Plaintiffs were offering Dr. Laposata's opinions on general causation, and Plaintiffs explained that they were not producing Dr. Laposata as a general causation expert. Given Plaintiffs' representation at the hearing, the Court finds this issue to be moot. As Plaintiffs agreed at the hearing, Dr. Laposata's testimony shall not exceed the scope of her designation, which is to provide case-specific testimony. Accordingly, the Court finds Defendants' Motion on this issue **DENIED AS MOOT.**

B. Dr. Rosenzweig

Defendants assert eight main challenges to Dr. Rosenzweig's opinions. First, Defendants argue that Dr. Rosenzweig's case-specific opinions impermissibly rely on his general opinions and the general opinions of others. Second, Defendants assert that Dr. Rosenzweig's opinions regarding the alternatives to the devices should be excluded because they do not constitute safer alternative designs and his opinions are speculative. Third, Defendants argue that Dr. Rosenzweig's opinions regarding the adequacy of the warnings should be excluded because he is not qualified to render such opinions and such opinions are irrelevant. Fourth, Defendants contend that Dr. Rosenzweig's opinions regarding the characteristics of the devices are not supported. Fifth, Defendants state that Dr. Rosenzweig should be precluded from speculating what Plaintiff's implanting physician knew prior to surgery. Sixth, Defendants argue that Dr. Rosenzweig's opinions regarding Plaintiff's long-term diagnosis are speculative. Seventh, Defendants state that

Dr. Rosenzweig cannot render any legal conclusions. Finally, Defendants assert that Dr. Rosenzweig cannot testify as to Defendants' knowledge, state of mind, or corporate conduct.

The Court will address Defendants' arguments separately.

1. Reliance on General Causation Opinions

Defendants assert that Dr. Rosenzweig relied on the MDL Prolift Expert Report of Daniel Elliott and the Gynemesh PS general report of Dr. Ostergard as well as his own TVT and TVT-O general causation reports. Defendants state that because Dr. Rosenzweig's case-specific opinions regarding Plaintiff incorporate and rely upon general opinions offered in other experts' reports filed in the MDL, Defendants incorporate by reference their *Daubert* motions to exclude these general opinions, which were previously filed in the main MDL docket. In addition, Defendants assert that Dr. Rosenzweig's opinions are redundant of the points he made in his general causation reports.

The Court finds that Defendants have not sufficiently explained why Dr. Rosenzweig's reliance on other experts or his own general causation opinions impermissible. *McPhereson v. Kelsey*, 125 F.3d 989, 995-96 (6th Cir. 1997) ("It is not sufficient for a party to mention a possible argument in a most skeletal way, leaving the court to ... put flesh on its bones."). Further, while Defendants incorporate by reference their *Daubert* motions to exclude the general opinions filed in the MDL court, the Court declines to search the MDL record to determine what motions and what specific opinions Defendants challenge. Accordingly, the Court finds Defendants' arguments not well taken, and the Motion on this issue is **DENIED**.

2. Alternatives to the Device

Defendants object to Dr. Rosenzweig's opinions regarding safer alternatives to the Device, arguing that his alternatives are not safer alternative designs, but instead, are procedures.

Defendants argue that in Tennessee, only similar products are relevant and alternative surgical procedures are not similar products, citing to *King v. Danek Medical, Inc*., 37 S.W.3d 429 (Tenn. Ct App. 2000). Defendants further argue that Dr. Rosenzweig's recommended surgeries eliminate the products in their entirety. In addition, Defendants state that Dr. Rosenzweig's opinions on UltraPro are also not design changes because the Prolift +M design is made with Ultrapro. Defendants state that the alternative surgical procedures suggested by Dr. Rosenzweig (autologous fasica slings and native tissue and suture-based repairs) should be excluded as these are not alternative designs. In addition, Defendants state that Repliform is not a mesh product and that it is a human dermal allograft. Defendants assert that Dr. Rosenzweig cites no studies to support his assertion that a lightweight polypropylene Ultrapo sling or a POP repair that had less stiff and rigid polypropylene or less polypropylene and did not incorporate the dangerous arms of Prolift is a safer alternative. Defendants further argue that there are insufficient studies to support that Ultrapo is safer.

In addition, Defendants assert that Dr. Rosenzweig's proposed alternatives are not feasible because they did not exist or were not cleared for use in the United States. Further, Defendants argue that Dr. Rozenweig's opinion that the purported safer alternatives would have altered Plaintiff's outcome is speculative ispe dixit.

Plaintiffs respond that they are not required under Tennessee law to offer evidence of safer alternatives. Plaintiffs argue that in states that do not require proof of safer alternatives to sustain a design defect claim, Dr. Rosenzweig's testimony has been upheld.

In the instant matter, Dr. Rosenzweig opined as follows:

> It is also my opinion that there were reasonably feasible alternatives available to Ethicon's TVT-O devices and for the treatment of Mrs. Ellis. For example, the Burch procedure would have been an appropriate treatment for the stress urinary incontinence. Another

> feasible alternative to the device would have included autologous fascia slings. Even lightweight polypropylene Ultrapro sling would have been a safer alternative to the Ethicon TVT-O sling for Mrs. Ellis.

[Doc. 95-2 at 27]. With respect to the Prolift +M, Dr. Rosenzweig opines as follows:

> Safer alternative designs, rather than the Prolift mesh kit, existed for this patient and were readily available without being cost-prohibitive. I have experience with many of these safer alternative designs and based on my experience and review of medical literature and other materials, it is my opinion that these alternative designs were safer and feasible for Mrs. Ellis. These safer alternative designs include:
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> - The use of sutures, including delayed absorbable sutures like PDS, in a uterosacral ligament suspension and a sacrospinous fixation; an anterior and posterior colporrhaphy; a sacrocolpopexy and a sacrohysteropexy;
> - Autologous fascia lata POP repair;
> - Repliform cadaveric fascia POP repair; and
> - POP repair that had less stiff and rigid polypropylene or less polypropylene (e.g., Ultrapro) and did not incorporate the dangerous arms of the Prolift.

[*Id.* at 29-30].

As mentioned above, Defendants object to the above testimony, arguing that it is irrelevant because Dr. Rosenzweig offers procedures and not designs, and Plaintiffs respond that in states that do not require proof of safer alternatives to sustain a design defect claim, Dr. Rosenzweig's testimony has been upheld. As an initial matter, the Court notes that the parties agree that under the Tennessee Products Liability Act, Plaintiffs are not required to prove the existence of an alternative design.

The Tennessee Products Liability Act states, in part, as follows, "A manufacturer or seller of a product shall not be liable for any injury to a person or property caused by the product unless

the product is determined to be in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller." Tenn. Code Ann. § 29-28-105(a). In determining if a product is defective or unreasonably dangerous, "Consideration is given also to the customary designs, methods, standards, and techniques of manufacturing, inspecting, testing by other manufacturers or sellers of similar products." Tenn. Code Ann. § 29-28-105(b).

The Court finds evidence of other procedures, as opposed to designs, irrelevant and confusing to the jury. *Hosbrook v. Ethicon, Inc.*, No. 3:20-CV-88, 2021 WL 1599199, at *4 (S.D. Ohio Apr. 23, 2021) ("To introduce evidence of alternative surgical procedures in a product liability case is irrelevant and would create confusion for the jury."). The Court agrees with Defendants that offering alternative procedures takes issue with Plaintiff's physician's treatment choices as opposed to the alleged issues with the Device. *See Willet v. Johnson & Johnson*, 465 F. Supp. 3d 895, 907 (S.D. Iowa 2020) ("The choice of a surgery over a device is a matter of medical judgment of treating doctors, not whether there is a safer alternative design for the product."). In addition, the Tennessee statute states that consideration should be given "to the customary designs, methods, standards, and techniques of manufacturing, inspecting, testing by other manufacturers or sellers of similar products." Tenn. Code Ann. § 29-28-105(b).

With respect to Dr. Rosenzweig's safer alternative designs, the parties also dispute whether he has offered products and/or designs. The main point of contention appears to be whether a substitute of natural material for synthetic material makes the product wholly different. During the motion hearing, Defendants explained that a native tissue repair is a procedure because a physician simply attaches the tissue with sutures. In addition, Defendants explained that the slings Dr. Rosenzweig mentions can either be made with the patient's own tissue (autologous slings) or with tissue from a cadaver (allograft slings). Defendants stated that these slings are not similar to

the syntenic mesh at issue and that the slings are regulated differently. The Court will not preclude Dr. Rosenzweig from testifying about the slings. The Court finds that the slings are relevant to the risk-utility analysis and that the differences between the devices at issue and the slings are facts that the jury should consider. In support of their position, Defendants rely on *King*, wherein the Tennessee Court of Appeals granted summary judgment to defendant on plaintiff's claim that a product was unreasonably dangerous, stating that the expert did not propose an alternative design but instead recognized dissimilar devices that did not use pedicle screws. 37 S.W.3d at 449. The Court notes, however, that *King* was decided on a dispositive motion, and here, the question is simply whether a product using non-syntenic material is relevant to the risk-utility analysis. The Court finds that it is relevant for the jury to consider.

Defendants also objected to Dr. Rosenzweig's opinion that Ultrapro is a safer alternative design, arguing his opinion is not reliable. Defendants stated at the hearing that Dr. Rosenzweig did not cite to any studies to support his opinion and that the Federal Drug Administration denied authorization of the Ultrapro during the relevant time period. As Plaintiffs noted at the hearing, the MDL court has allowed Dr. Rosenzweig to offer the UltraPro mesh as an alternative. *See Ellis v. Ethicon,* No. 2:20-cv-223-CEA-HBG [Doc. 66-20 at 7-8]. With respect to Defendants' arguments regarding FDA approval and that the Prolift +M uses UltraPro, the Court finds that those issues are better addressed through cross examination. Finally, Defendants object to Dr. Rosenzweig's statement that if the alternative designs had been used, Plaintiff would not have sustained her injuries. Defendants argue that Dr. Rosenzweig's opinion is speculative, but the Court finds that Defendants can address this issue during cross examination. Accordingly, the Court finds Defendants' arguments well taken, in part, and the Motion on this issue is **GRANTED IN PART AND DENIED IN PART.**

3. Adequacy of the Instructions for Use

Defendants assert that Dr. Rosenzweig's warnings opinions should be excluded because he is not qualified about the adequacy of the instructions for use ("IFU"). In addition, Defendants argue that Dr. Rosenzweig's opinions are not relevant because the implanting physicians testified that none of the suggested warning changes would have changed their prescribing decision. Plaintiffs respond that multiple federal courts, including the MDL court, have held otherwise.

In his expert report, Dr. Rosenzweig opines as follows:

> Ethicon failed to include and/or describe the significant adverse events and risks in its Instruction for Use (IFU) for the device. Ethicon did not fully inform physicians about numerous adverse reactions/risks associated with the TVT-O despite the fact that Ethicon had scientific knowledge of the risks from the time the product was first sold. As a result, physicians were unable to fully consent and inform patients of the risk associated with TVT-O. In addition, some risks included by Ethicon in the IFU are mischaracterized to minimize the actual risk. Finally, when given numerous opportunities to update the IFU, and in the face of specific requests to do so from numerous medical professionals, Ethicon did not make the necessary updates. To a reasonable degree of medical certainty, this prevented physicians and patients the ability to make an informed choice regarding the use of the TVT-O. For a surgeon to properly inform the patient of all the known risks included in any procedure involving an implantable medical device, the surgeon relies upon the manufacturer to have scientific knowledge of and convey all characteristics of its products that could impact safety and efficacy. Specifically, surgeons rely on the "Adverse Events/Risks" section of a medical device IFU to gain scientific. knowledge regarding adverse events or undesirable effects that the company knows are associated with the product.
>
> For these reasons, and as fully outlined in my general expert report, Ethicon failed to advise Mrs. Ellis's implanting physician of the adverse events and risks associated with the TVT-O. Dr. Knight consented Mrs. Ellis for the procedure, but according to the IFU, he could not have properly consented her because he was not fully aware given the IFU information.

[Doc. 95-2 at 27].

With respect to the Prolift +M, Dr. Rosenzweig opines as follows:

> Mrs. Ellis was not able to make a fully informed decision regarding the implantation of either the Prolift or the TVT-O because Ethicon failed to fully disclose the risks and complications (both early and late) in their Instructions for Use. As discussed above and elsewhere in this report, Mrs. Ellis did not receive information about the above risks because Ethicon did not disclose them fully in its Instructions for Use. Surgeons, including Dr. McCauley and Dr. Knight, were not made aware of them. This is true despite information readily available to Ethic about these risks, which predate the launch of the devices. Because of this, Dr. McCauley and Dr. Knight could not pass along this information to Mrs. Ellis and properly inform her about the risks associated with the Prolift.

[*Id.* at 30-31].[2]

As an initial matter, Defendants assert that Dr. Rosenzweig's opinion is irrelevant given the undisputed testimony from the implanting physicians that none of the suggested warning changes proposed by Plaintiffs would have changed their prescribing decisions. The Court agrees with Plaintiffs that this issue has been raised in the dispositive motion, and a ruling on the dispositive motion will ultimately determine whether Dr. Rosenzweig's opinion is relevant. *See* [Doc. 100 at 5] (Plaintiffs' Response) (stating that if the Court were to grant the motion for partial summary judgment with respect to Plaintiffs' failure to warn and fraudulent concealment claims, Dr. Rosenzweig would not offer such testimony). Otherwise, Defendants may cross examine Dr. Rosenzweig with the implanting surgeons' testimonies.

Defendants also assert that Dr. Rosenzweig is not qualified to opine on the adequacy of the IFU. The Court disagrees. As the parties acknowledged, the MDL court addressed a similar challenge to Dr. Rosenzweig's qualifications. Specifically, the court held, "Dr. Rosenzweig is qualified to opine about the risks of the TVT–O and pelvic mesh surgery and whether those risks

[2] The Court will address Dr. Rosenzweig's opinions regarding the implanting surgeons' knowledge below.

were adequately expressed on the TVT–O's IFU." *Huskey v. Ethicon, Inc.,* 29 F. Supp. 3d 691, 704 (S.D.W. Va. 2014). The court noted that while Dr. Rosenzweig had not personally drafted an IFU, he had consulted on products warnings in the past. *Id.* at 703-04. The Court further noted that Dr. Rosenzweig served on another company's scientific advisory committee that worked on similar documents and he had reviewed numerous IFU for a variety of products, including mesh products in order to understand the proper way to use the device and gain knowledge about the complications and adverse events associated with the device. *Id.* The Court finds no basis to depart from the decision in *Huskey.* Accordingly, the Court finds Defendants' argument not well taken, and the Motion on this issue is **DENIED**.

4. The Devices' Characteristics

Defendants argue that Dr. Rosenzweig's opinions concerning contraction, shrinkage, degradation, deformation, rigidity, and other alleged characteristics of the mesh should be excluded. Defendants state that while Dr. Rosenzweig opines that Plaintiff's claimed injuries resulted from the issues with the mesh, he does not point to any evidence that Plaintiff's mesh had any of the above characteristics. Further, Defendants argue that the MDL court rejected specific causation opinions on similar facts, citing to *Huskey*, 29 F. Supp. 3d at 691.

Plaintiffs respond that Dr. Rosenzweig explains how the mesh's conditions can lead to the specific injuries, relying on Plaintiff's medical records and the condition of the mesh at explant. In addition, Plaintiffs argue that Dr. Rosenzweig has expertise to recognize these types of complications when he encounters indications of them in a patient's records.

Defendants state that Plaintiffs have not addressed Dr. Rosenzweig's reliance on the general reports of Dr. Elliot and Dr. Ostergard for his opinions. Defendants state that the general reports are subject to *Daubert* motions. Defendants state that Dr. Rosenzweig did not submit a general

report on Prolift +M, so he cannot testify regarding any general opinions on this device. Defendants maintain that Dr. Rosenzweig's opinions are unreliable.

Specifically, Defendants object to the following opinions in Dr. Rosenzweig's expert report:

> As explained further below, the Ethicon Prolift device is subject to polypropylene mesh characteristics that led to Mrs. Ellis's injuries, including: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) deformation, rigidity, bunching and banding of the mesh; (d) loss of pore size with tension; (e) fibrotic bridging leading to scar plate formation and mesh encapsulation; (f) shrinkage/contraction of the encapsulated mesh; and (g) the difficulty and/or impossibility of removing the devices. As a result of these and other inadequacies with the mesh, it is my opinion to a reasonable degree of medical certainty that the implantation of the Prolift device caused Mrs. Ellis to suffer numerous injuries which are permanent in nature. These injuries include the injuries discussed below, such as pelvic pain, dyspareunia, pudendal neuralgia, and urinary incontinence.

[Doc. 95-2 at 5-6]. In forming his opinion, Dr. Rosenzweig states that he relied on the scientific literature, corporate documents from Ethicon, case-specific materials (medical records and depositions), and his clinical experience in the treatment of pelvic pain and urinary incontinence. [*Id.* at 6]. Dr. Rosenzweig explains Plaintiff's medical history, dating back to 2008. [*Id*. at 6-21]. In Plaintiff's case, he conducted a differential diagnosis and opined that the above characteristics caused Plaintiff's pelvic pain, pain with intercourse, pudendal neuralgia, and stress urinary incontinency. [*Id.* at 24].

With respect to the Prolift +M, Dr. Rosenzweig states that he also performed a "broad differential diagnosis" and considered her medical history after the mesh implant procedures." [*Id.* at 28]. Dr. Rosenzweig opines as follows:

> As a result of the Prolift implant, including the mesh characteristics discussed below, and the subsequent reactions and surgical revisions, Mrs. Ellis has sustained the following injuries: persistent pelvic pain, pain with intercourse, pudendal neuralgia, and urinary incontinence. It is my opinion, to a reasonable degree of medical

> certainty, that the debilitating injuries suffered by Mrs. Ellis, which are listed above, were directly and proximately caused by the Prolift, including the following polypropylene mesh characteristics: (a) degradation of the mesh; (b) chronic inflammation and chronic foreign body reaction; (c) deformation, rigidity, bunching and banding of the mesh; (d) loss of pore size with tension; (e) fibrotic bridging leading to scar plate formation and mesh encapsulation; (f) shrinkage/contraction of the encapsulated mesh; and (g) the difficulty and/or impossibility of removing the devices.
>
> To a reasonable degree of medical certainty, contraction, shrinkage, deformation, degradation, and rigidity of the Prolift, the materials used to manufacture the Prolift, and the design of the Prolift, or a combination of these factors, caused Mrs. Ellis's injuries listed above.

[*Id.* at 29].

The Court finds that Defendants' challenges go to the weight of Dr. Rosenzweig's opinions rather than to their admissibility. As an initial matter, and as stated above, Defendants do not explain why it was error for Dr. Rosenzweig to rely on other experts' reports. In any event, however, in his report, Dr. Rosenzweig relies on his extensive knowledge regarding complications with these devices, the medical literature, and his review of Plaintiff's medical records. Specifically, in this case, Dr. Rosenzweig performed a differential diagnosis with respect to the alleged complications of the TVT-O and the Prolift +M. The Sixth Circuit Court of Appeals has held that a "medical-causation opinion in the form of a doctor's differential diagnosis is reliable and admissible, where the doctor: (1) objectively ascertains, to the extent possible, the nature of the patient's injuries; (2) 'rules in' one or more causes of the injury using a valid methodology; and (3) engages in "standard diagnostic techniques by which doctors normally rule out alternative causes to reach a conclusion as to which cause is most likely." *Best v. Lowe's Home Centers, Inc.,* 563 F.3d 171, 179 (6th Cir. 2009) (quoting *In re Paoli Railroad Yard PCB Litig.,* 35 F.3d 717 (3d Cir. 1994)). Accordingly, the Court finds Dr. Rosenzweig's opinion reliable.

The Western District of Texas addressed similar arguments regarding Dr. Rosenzweig's opinion. *See Meindertsma v. Ethicon Inc*., No. 1:20-CV-00708-RP, 2021 WL 2010355, at *7 (W.D. Tex. May 17, 2021). Specifically, in *Meindertsma*, Ethicon argued that Dr. Rosenzweig's opinions were unreliable because there is no evidence that degradation, deformation, rigidly, fraying, and other characteristics existed in the specific device that the surgeon implanted in plaintiff. *Id*. The court disagreed. *Id*. The court held that although Dr. Rosenzweig did not personally examine the mesh or the plaintiff, his differential diagnosis was reliable and that Ethicon's challenges were to the weight of the opinion. *Id.*

Similarly, in the instant matter, Dr. Rosenzweig discussed the conditions he was able to rule out, and he established a basis for ruling in the characteristics of the mesh that causes the type of injuries that Plaintiff allegedly suffered. Defendants may cross examine Dr. Rosenzweig on the characteristics of the devices. Accordingly, the Court finds Defendants' arguments not well taken, and the Motion on this issue is **DENIED**.

5. Knowledge of Implanting Physician

Defendants assert that Dr. Rosenzweig should not be allowed to speculate on what Plaintiff's implanting physician knew prior to surgery. Specifically, Defendants object to Dr. Rosenzweig's opinion that the implanting physicians were not aware of the risks associated with the mesh and that Plaintiff did not receive the risks. Defendants argue that such testimony is improper state of mind testimony and speculative. In addition, Defendants state that Plaintiff's surgeons testified that additional warnings would not have changed their treatment decisions or their recommendations. Defendants argue that the jury can evaluate the implanting surgeon's testimony about their knowledge of the risks and that the MDL court consistently ruled that such testimony was impermissible.

Plaintiffs argue that Dr. Rosenzweig's opinion that Plaintiff's implanting physician had inadequate information to warn about the relevant risks is supported by the facts. Plaintiffs state that Dr. Rosenzweig seeks to testify about the knowledge of the medical community at large regarding the complications of Ethicon's devices.

In the present matter, Dr. Rosenzweig opines that Plaintiff's "implanting physician, Dr. Knight, did not know about many of these risks before he implanted Ms. Ellis with the device." [Doc. 95-2 at 28]. Dr. Rosenzweig later opines surgeons like Dr. McCauley and Dr. Knight were not made aware of the risks associated with the devices. [*Id*. at 31]. He discusses the specific risks with Prolift and concludes that Dr. McCauley was not aware of such risks. [*Id.*].

The Court finds such testimony not permissible. *See Bell v. Ethicon Inc.,* No. 4:20-CV-3678, 2021 WL 1111071, at *8 (S.D. Tex. Mar. 23, 2021) (excluding Dr. Rosenzweig's testimony regarding what the implanting surgeon knew or did not know at the time of plaintiff's surgery); *Nall v. C. R. Bard, Inc*., No. 2:13-CV-01526, 2018 WL 524632, at *2 (S.D. W.Va. Jan. 23, 2018) ("The defendant argues that I should preclude Dr. Rosenzweig from testifying as to the state of mind of the plaintiff and Dr. Foster, her implanting physician. I agree; experts may not testify about what other parties did or did not know."). The Court finds that the jury can evaluate the implanting surgeons' testimony about their knowledge of the risks at the time of Plaintiff's implant procedures. Accordingly, the Court finds Defendants' arguments well taken, and the Motion on this issue is **GRANTED**.

6. Plaintiff's Long-Term Diagnosis

Defendants seek to exclude Dr. Rosenzweig's opinions regarding Plaintiff's long-term prognosis as ipse dixit. Defendants state that Dr. Rosenzweig provides no support for these conclusions. Defendants further state that Dr. Rosenzweig did not conduct an independent medical

examination and that he does not cite to any medical opinions that state Plaintiff has a permanent injury from the TVT-O or Prolift +M.

Plaintiffs respond that Dr. Rosenzweig's opinions are to a reasonable degree of medical certainty. Plaintiffs state that Dr. Rosenzweig's opinions regarding Plaintiff's long-term diagnosis are based on his personal training, experience, review and knowledge of the medical literature, and his examination of Plaintiff's medical records.

In his expert report, Dr. Rosenzweig opines, "As a result of the defects of the TVT-O, Ms. Ellis suffered and continues to suffer life-long injuries." [Doc. 95-2 at 23]. Dr. Rosenzweig states that Plaintiff "will have continued and ongoing complications, necessitating the need for future medical treatments related to the permanent complications she suffered from the inadequacies and implantation of that TVT-O device." [*Id*. at 24]. Further, Dr. Rosenzweig states as follows:

> As the TVT-O device has not been fully removed, she will continue to suffer from long term risks of future erosion/exposure, infection, abscess formation, vaginal pain and bleeding, pelvic pain, groin and thigh pain. She will likely also continue to experience chronic foreign body reaction and chronic inflammation. She will have the possibility of future risks and symptoms as long as there is mesh material left in her body. As a result, Mrs. Ellis may need additional surgeries to remove the TVT-O mesh, and to treat the persistent pelvic pain, pain with intercourse urinary frequency, urgency and urinary incontinence, requiring multiple revision procedures. Mrs. Ellis will likely require pelvic floor therapy and physical therapy to alleviate her symptoms stemming from the implant of the TVT-O device.
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> ***
>
> I highly recommend that Mrs. Ellis be followed up with a continuum of care, including but not limited to, pelvic floor physical therapy, counseling, biofeedback therapy, and/or Botox therapy for her chronic pain, which may or may not be ultimately successful. This continuum of care could range anywhere from 6 months to 5 years. This continuum of care is time-consuming, socially disruptive, very expensive, and not usually covered by insurance.

[*Id.* at 26].

With respect to Prolift +M, Dr. Rosenzweig explains, "It is highly unlikely, even with aggressive physical therapy, biofeedback, medication use and/or surgical intervention, for Mrs. Ellis to have complete resolution of the mesh erosions without the risk of future erosions." [*Id.* at 30]. He makes similar conclusions with respect to Plaintiff's pelvic pain, dyspareunia, urinary frequency, and other pelvic and vaginal problems. [*Id.*].

The Court finds Defendants' objections go to the weight of the evidence and not to the admissibility of the evidence. Dr. Rosenzweig has thoroughly examined Plaintiff's medical records and is "familiar with the medical complications that are generally associated with mesh repair surgery," and he is "experienced in the recognition, diagnosis, treatment of patients suffering from complications caused by pelvic mesh implants." [Doc. 95-2 at 3]*; see also Bell v. Ethicon Inc.,* No. 4:20-CV-3678, 2021 WL 1111071, at *10 (S.D. Tex. Mar. 23, 2021) ("Dr. Rosenzweig's prognosis is sufficiently grounded in his expertise."). Given Dr. Rosenzweig's experience, knowledge, and review of Plaintiff's medical records in this case, the Court finds his testimony permissible and that Defendants may cross examine Dr. Rosenzweig regarding his opinions. Accordingly, the Court finds Defendants' arguments not well taken, and the Motion on this issue is **DENIED**.

7. Legal Conclusions

Defendants argue that Dr. Rosenzweig should not be able to testify as to any legal conclusions. For instance, Defendants assert that Dr. Rosenzweig states, "Ethicon failed to act as a reasonable and prudent medical device manufacturer by manufacturing and selling its polypropylene mesh in permanent prosthetic implants like the TVT-O." [Doc. 96 at 21]. In addition, Defendants submit that Dr. Rosenzweig states that the implanting physicians did not sufficiently understand the risks of the devices and were not fully informed. Defendants assert

that by opining that the IFU is insufficient to allow a physician to properly counsel a patient, Dr. Rosenzweig is necessarily stating that the IFU is inadequate and that Plaintiff's implanting physicians were not sufficiently informed. Defendants argue that these are legal conclusions.

Plaintiffs respond that Dr. Rosenzweig will not offer legal conclusions at trial and that Defendants' motion should be declared moot in this respect. Plaintiffs state that Dr. Rosenzweig has testified many times at trial and that Plaintiffs' counsel understands the limitations that the Court has placed on the expert testimony.

During the hearing, the parties agreed that the experts will not offer legal conclusions. Accordingly, the Court finds this issue to be moot, and the Motion on this issue is **DENIED AS MOOT.**

8. Defendants' Knowledge

Defendants state that Dr. Rosenzweig should be precluded from testifying to Defendants' knowledge, state of mind, or corporate conduct. Defendants state that precluding such testimony is consistent with the MDL court's prior rulings.

During the hearing, Defendants stated that the parties agree that Dr. Rosenzweig cannot offer testimony on Defendants' knowledge, state of mind, or corporate conduct. Plaintiffs stated that the parties generally agreed during the MDL proceedings that such testimony is improper, but in this case, Defendants do not identify any specific testimony that Dr. Rosenzweig intends to offer on such subjects, and therefore, Defendants' request should be denied on that ground.

The Court finds this issue moot. Defendants have not identified any specific testimony Dr. Rosenzweig seeks to offer with respect to their knowledge, state of mind, or corporate conduct, and the parties generally agree that such testimony is not permissible. Accordingly, the Court finds this issue to be moot, and the Motion on this issue is **DENIED AS MOOT.**

IV. CONCLUSION

Accordingly, for the reasons explained above, the Court **GRANTS IN PART AND DENIES IN PART** Defendants' Renewed Motion to Limit the Opinions of Pathologist Elizabeth A. Laposata, M.D. [**Doc. 93**] and Defendants' Motion to Limit the Case-Specific Opinions of Bruce Rosenzweig, M.D. [**Doc. 95**].

IT IS SO ORDERED.

ENTER:

Bruce Guyton

United States Magistrate Judge